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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/743,599 | 12/22/2003 | Robert W. Olsen | P-11209.06 | 7548 |
| 27581 | 7590 | 05/10/2006 | EXAMINER | |
| MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924 | | | DEAK, LESLIE R | |
| | | | ART UNIT | PAPER NUMBER |

3761

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,599

Applicant(s)

OLSEN ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 8, 17, 18, 21, 28, 36-38, 41, 47 and 58 is/are rejected.
- 7) ☒ Claim(s) 2, 5-7, 9-16, 19, 20, 22-27, 29-35, 39, 40, 42-46, 48-57, 59-61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/12/04 and 2/14/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 17, 18, 21, and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,730,267 to Stringer et al.

In the specification and figures, Stringer discloses the apparatus and method as claimed by applicant. In particular, with regard to claims 1 and 18, Stringer discloses a blood handling system 30 as a component of an extracorporeal blood circuit 10 (see column 4, lines 32-37). The blood handling system comprises a housing 40 that defines a chamber or gas collection plenum 50 with a gas removal port 46 connected to the plenum (see, generally, column 5, FIG 3). The port comprises an air sensor 37 and a valve 36. The gas removal port is connected to suction line 35 that is connected to a vacuum source 34 (see FIG 1). The valve and the sensor are coupled to controller 33 so that the controller can operate the valve in response to the sensor (see column 5, lines 3-15). The controller comprises a display 225 that serves as a display of system function and may comprise a graphic display (comprising an alerting means) that displays help (or error) messages (see column 10, lines 28-43, column 11, lines 1-10).

With regard to the method of claims 21 and 36-38, Stringer discloses the process of supplying the air removal device and operating the device based on feedback from sensor 37 that opens and closes valve 36 (see column 7, lines 15-28).

With regard to the claim limitations drawn to the action of the controller, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the controller and display disclosed by Stringer is capable of performing the functions claimed by applicant, meeting the limitations of the claim.

With regard to claims 17, 36, and 37, Stringer discloses that the system comprises a back-up battery in base 220 and that the display includes an indicator of battery status, which may comprise an alert if the backup battery is failing (see column 10, lines 28-55).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 8, 21, 28, 41, 47, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,337,049 to Tamari.

In the specification and figures, Tamari discloses the apparatus and method as claimed by applicant. In particular with regard to claim 1, Tamari discloses a venous reservoir 1819 with outer walls 18, 19 that enclose a chamber 2. The reservoir

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comprises a purge port or outlet tube 4 connected to the chamber 2 with a sensor or detector 10 and monitor/controller 10 that alerts the user to the presence of air entering the tube (see column 10, lines 5-35). The purge port may be connected to a suction source 1114 (see FIGS 1, 2, column 9, lines 20-23). The assembly further comprises valve or clamp (not shown) on the purge line that may be opened and closed in response to signals from monitor/controller 12 (see column 10, lines 25-27). The monitor/controller 12 may generate an alarm signal when air enters the outlet tube, alerting the user to the status of the device.

With regard to the claim limitations drawn to the action of the controller, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the controller/monitor disclosed by Tamari is capable of performing the functions claimed by applicant, meeting the limitations of the claim.

With regard to the method of claims 21, 28, 41, 47, and 58, Tamari discloses the process of supplying the air removal device and operating the device based on feedback from sensor 10 that opens and closes the suction valve.

With regard to claims 8, 28, and 58, Tamari discloses that purge valve may comprise a solenoid actuated tubing clamp, meeting the limitations drawn to a pinch valve and the method of opening the pinch valve (see column 10, lines 25-28).

With specific regard to claim 41, Tamari discloses that the system allows for automatic elimination of air from the extracorporeal system with little to no user

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intervention, indicating that movement of the purge valve between open and closed based on controller signals operates automatically, as claimed by applicant.

With specific regard to claim 47, Tamari specifically discloses that the method includes the step of alerting the user or perfusionist under certain circumstances, such as the presence of air in the purge port. Such circumstances may be considered an "error state" as claimed by applicant. Therefore, the Tamari disclosure meets the limitations of the claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,337,049 to Tamari, as applied above.

In the specification and figures, Tamari discloses the apparatus and method substantially as claimed by applicant. Tamari discloses that sensor 10 is responsive to detect the presence of air as well as the presence of rising liquid (see column 10, lines 1-28). Tamari does not disclose a separate liquid sensor. It has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. One of ordinary skill in the art may separate the integrated sensor disclosed by Tamari into two separate sensors as claimed by applicant in order to independently

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monitor fluid and air in the line. Since the detector disclosed by Tamari is capable of functioning as claimed by applicant, it meets the limitations of the claim.

With regard to the claim limitations drawn to the action of the controller, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, applicant merely claims that the controller performs the claimed functions, and does not set forth or claim specifically that the controller is "programmed to" perform the claimed functions. Absent a structural limitation (such as the "programmed to" language suggested above) between the instant controller and the controller disclosed by Tamari, examiner considers the Tamari structure capable of being programmed to and perform the functions claimed by applicant. Since the controller/monitor disclosed by Tamari is capable of performing the functions claimed by applicant, the Tamari disclosure meets the limitations of the claims.

Allowable Subject Matter

7. Claims 2, 5-7, 9-16, 19, 20, 22-27, 29-35, 39, 40, 42-46, 48-57, and 59-61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest an active air removal system with the housing, sensor, valve, and control system, as claimed by applicant, along with the

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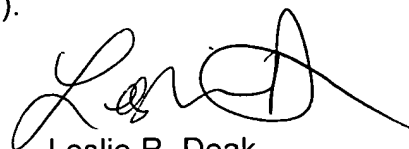
mechanical release button, various additional sensors, power supply with backup battery as claimed, alert system as claimed, as well as the other steps and limitations of the claims. The prior art also fails to disclose or suggest particular details of the operating method claimed by applicant in the indicated allowable claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak
Patent Examiner
Art Unit 3761
1 May 2006

TATYANA ZALUKAEVA
SUPERVISOR, PRIMARY EXAMINER

